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# 18

October 14, 1988

Alphonse R. Noe, Manager  
Patent Law Department  
AMERICAN CYANAMID COMPANY  
1937 West Main Street  
P.O. Box 60  
Stamford, CT 06904-0060

RE: Patent Term Extension  
Application for  
U.S. Patent No. 4,197,249  
Issued: April 8, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,197,249 issued April 8, 1980, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on April 22, 1988 as follows:

$$\begin{aligned} \text{Period} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1509) + 1309 \\ &= 2064 \text{ days} \end{aligned}$$

Since the regulatory review period began (May 16, 1979) before the patent issued (April 8, 1980), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the extension period. 35 U.S.C. 156(c) (From May 16, 1979 to April 8, 1980 is 327 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 1836-327=1509 days). No determination of a lack of due diligence was made. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(4)(c) applies in the present situation because Patent No. 4,197,249 was issued (April 8, 1980) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Novantrone became effective (May 16, 1979), was before date of enactment, and the product was not approved for commercial marketing or use (December 23, 1987) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,197,249 and Novantrone cannot exceed two (2) years under 35 USC 156(g)(4)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,197,249 may be made if filed within one (1) month of the date of this notice. 37 CFR 1.136(a) is not applicable to this time period. It is noted that the applicant for extension of the term of Patent No. 4,197,249 has filed an application for extension of the term of Patent No. 4,278,689, also to the product Novantrone. Only one patent may be extended for any product. 35 USC 156(c) 4. In the absence of an election by applicant, and in accordance with 37 CFR 1.785 (b), if applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension of patent term will be issued to the patent having the earliest date of issuance (4,197,249). If issuance of the certificate of extension on U.S. Patent 4,197,249 occurs, the following information will be published in the Official Gazette:

U.S. Patent No. 4,197,249, granted  
April 8, 1980 to Keith C. Murdock et al  
Owner of Record: American Cyanamid Company  
Title: 1,4-BIS(SUBSTITUTED-AMINO)-5,8-DIHY-  
DROXY-ANTHRAQUINONES AND LEUCO BASES  
THEREOF  
Classification: 260-380  
Product Trade Name: Novantrone  
Term Extended: 2 years

C.E. Van Horn

Charles E. Van Horn  
Deputy Solicitor  
Patent & Trademark Office

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Novantrone  
FDA Docket # 88E-0132